

*Methods and Instrumentation* Vol. 1, No. 3 pp. 172-176.

These rejections are respectfully traversed for the following reasons.

A. Effenhauser

The Examiner states that the applicant cannot rely upon the foreign priority papers to overcome the rejection based on the Effenhauser references because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. However, the foreign paper relied on for priority in the instant case is European Patent Application No. 93810272.0. A certified copy of this application, in English, was submitted in parent application number 08/226,605 on August 16, 1995. A copy is submitted herewith.

Section 102(a) requires that a "person shall be entitled to a patent unless the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent."

Both of the Effenhauser references were published after the priority date of the instant application. Thus, the Effenhauser references are not effective Section 102(a) references.

B. Vergeggen

The Examiner states that Verheggen illustrates all of the structures recited in claim 19 and shows an experiment where the sampling was carried out by electromigration. Specifically, the Examiner has stated that Applicants' argument that recognition of the manipulation of supply and drain channel intersections with the electrolyte channel to form a geometrically defined sample volume between the supply and drain ports, which is lacking in Verheggen, has not been well-taken because applicant has failed to point out where this limitation is recited in the claims, and Verheggen was described as first showing the volume defined injection principle.

The Examiner also rejects Applicants' argument that Verheggen advises against the use of an electrokinetic technique to introduce the sample because Verheggen states that such electrokinetic techniques do not result in the introduction of representative sample aliquots. The Examiner states that Applicants' argument does not change the fact that Verheggen *et al.* did perform the claimed process and that Verheggen only advised against using electromigration in quantitative analysis.

B1. The Invention

The invention describes a method of injecting a defined volume of sample into an

electrolyte channel in a microfluidics device. The method comprises (i) placing a sample in a sample channel that intersects the electrolyte channel at a supply port, (ii) injecting sample in the sample channel along a pathway that includes the supply port, a drain port intersecting the electrolyte channel at location axially spaced from the first port, and a segment of the electrolyte channel between the two ports, where the sample volume is defined as the region of the electrolyte channel extending between and along the two ports, by applying an electric field across the supply and drain channels, (iii) by said injecting, producing a defined sample volume in the electrolyte channel, and (iv) electrokinetically moving the defined sample volume along the electrolyte channel by applying an electric field across a reservoir for the electrolyte buffer and a drain at an opposite end of the electrolyte channel.

## B2. The Prior Art

Verheggen discloses a sampling device for capillary isotachopheresis and capillary zone electrophoresis whereby the most essential feature of this device is the direct introduction of the sample solution into a part of the capillary tube by means of two feeders which extend perpendicular to the capillary tube. The arrangement of the two feeders off-set from each other along the longitudinal extension of the capillary tube is such that the sampling device has the shape of a capillary double T structure.

## B3. Analysis

The standard for lack of novelty, that is, for anticipation, is one of strict identity. *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F2d 1367, 231 USPQ 81, 90 (Fed. Cir. 1986) *In re Donohue*, 766 F2d 531, 226 USPQ 619, 621 (Fed. Cir. 1985). To anticipate a claim for a patent, a single prior source must contain all its essential elements.

Both of the Examiner's rejections with regard to this exact reference, Verheggen *et al.*, have been previously addressed in the September 21, 2000 opinion before the Board of Patent Appeals and Interferences (Appeal No. 1997-3328) during prosecution of parent application number 08/226,605.

### B3(i). Forming a Geometrically Defined Sample Volume

With regard to forming a geometrically defined sample volume, the limitation may be found below, in bold type, underlined and italicized.

19. A method of injecting a defined volume of sample into an electrolyte channel in a

microfluidics device, comprises

- (i) placing a sample in a sample channel that intersects the electrolyte channel at a supply port,
- (ii) injecting sample in the sample channel along a pathway that includes the supply port, a drain port intersecting the electrolyte channel at location axially spaced from the first port, and a segment of the electrolyte channel between the two ports, where the sample volume is defined as the region of the electrolyte channel extending between and along the two ports, by applying an electric field across the supply and drain channels,
- (iii) by said injecting, producing a defined sample volume in the electrolyte channel, and
- (iv) electrokinetically moving the defined sample volume along the electrolyte channel by applying an electric field across a reservoir for the electrolyte buffer and a drain at an opposite end of the electrolyte channel.

With regard to the Examiner not taking Applicants' argument on this point well, Applicants' direct the Examiner's attention to page 6 of Appeal No. 1997-3328, stating, "Although the prior art appears to recognize the different migration rates within a sample, and that the sample should be clearly defined, *we do not find any prior art recognition of how to provide a geometrically defined sample* in a[n] electrophoresis device as described in claim 19." (emphasis added).

#### B3(ii). Electrokinetic Movement

The Appeal Board also previously addressed the issue of Verheggen's discussion of the use of electromigration when reversing the Examiner's rejection. As noted on page 7 of Appeal No. 1997-3328, the Board stated, "Verheggen points to the disadvantages of using electromigration technique for the sample and refers to alternatives rather than ways to improve the electromigration technique."

In *Bausch & Lomb v. Barnes-Hind/Hydrocurve, Inc.*, 796 F2d 443, 230 USPQ 416 (Fed. Cir. 1986), the court stated "a reference should be considered as a whole, and portions arguing against or teaching away from the claimed invention must be considered."

Thus, as clearly articulated by the Board of Appeals, Verheggen fails to disclose at least two elements of the invention: (i) producing a defined sample volume in the electrolyte channel; and (ii) electrokinetically moving the defined sample volume along the electrolyte channel.

Accordingly, Applicants respectfully request withdrawal of the rejections under 35 U.S.C. §§102(a) and 102(b).

II. Double-Patenting Rejection

Claims 19-21 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 4 and 5 of U.S. Patent No. 6,423,198. The Examiner noted that a timely filed Terminal Disclaimer in compliance with 36C.F.R. §1.321(c) would overcome an actual or provisional rejection on this ground.

Enclosed herewith is an executed Terminal Disclaimer filed in accordance with C.F.R. §1.321(b) and (c) which disclaims the terminal portion of any patent issuing on the instant application that extends beyond the expiration of U.S. Patent No. 6,423,198.

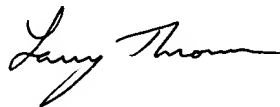
The applicants submit that the Terminal Disclaimer overcomes the rejection for obviousness-type double patenting and withdrawal of the rejection is respectfully requested.

III. Conclusion

In view of the above remarks, the applicants submit that the claims are in condition for allowance. A Notice of Allowance is, therefore, respectfully requested.

If in the opinion of the Examiner a telephone conference would expedite the prosecution of the subject application, the Examiner is encouraged to call the undersigned at (650) 838-4405.

Respectfully submitted,



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